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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WEBMAN, EDWARD J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/25/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928467

Applicant(s)

SPIREAS

Examiner

WEBMAN

Group Art Unit

167

---The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address---

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/22/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-81 is/are pending in the application.
- Of the above claim(s) 5, 25, 45-52, 59, 67 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-4, 6-24, 26-44, 53-58, 60-66, 68-81 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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Claims 1-4, 6-24, 26-44, 53-58, 60-66, 68-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 21, 53, 57, 65, 68, 69 "susceptible" is vague. Under what conditions? Applicant argues that one of ordinary skill would know which amino acids degrade to form Lactams. However, it is the conditions under which the degradation occurs that is at issue. One of ordinary skill cannot ascertain the metes and bounds of those conditions from the claim language.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-20, 53-58, 60-64, 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Vilkov (US Patent No. 6,294,198 B1).

Vilkov teaches gabapentin processing with ethanol (title, abstract, column 5, lines 35-37), starch (column 6, line 20), and calcium stearate (column 6, line 14). A tablet is specified (abstract).

- As to the claimed properties, the anticipatory composition must possess these properties because it is the same composition as that claimed.

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- As to the claimed crystalline anhydrous form, the active is well-known in the art as such.

Applicant argues at least 20ppm of an anion. However, the amount of stearate ion in table 1 column 8 exceeds the claimed amount of anion. Applicant also argues that the ethanol of Vilkov is removed. However, column 9 lines 28-30 indicate residual moisture remains. Further, applicants disclose drying on page 14 line 12. Thus, the claimed invention, like Vilkov, appears to contain residual ethanol elected by applicant.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 65-66, 68-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Vilkov (US Patent No. 6,294,198 B1).

Vilkov teaches gabapentin processing with ethanol (title, abstract, column 5, lines 35-37), starch (column 6, line 20), and waxes as a lubricant (column 6, line 12-14).

Waxes are equivalent to calcium stearate. A tablet is specified (abstract).

- Gabapentin is well-known to be available as crystallized from ethanol as the base, that is, not as a salt.
- As to the claimed properties, the anticipatory composition must possess these properties because it is the same composition as that claimed.

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The rebuttal regarding applicant's ethanol argument in the previous 102 rejection is incorporated herein.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-24, 26-44, 53-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilkov (US Patent No. 6,294,198 B1).

Vilkov is discussed above in the first 102.

- As to the claimed chloride, gabapentin is available as a chloride salt (see Satzinger et al. US Patent No. 4,087,544, column 2, line 10). It is well-known in the art that the salt of an organic compound is more soluble than the organic compound itself. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the chloride salt of gabapentin as the active agent in Vilkov to achieve the beneficial effect of a more soluble active.

Applicant argues that Vilkov does not teach at least 20 ppm anion. However, the Chloride form of Gabapentin in the obvious composition provides the claimed anion. Applicant also argues that there is no motivation in Vilkov to modify Vilkov. However, the motivation to combine is based on the well-known fact that salts of organic compounds are more soluble in water than the organic compound itself.

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Claims 78-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 78-81 Toluene Sulfonate and Benzene Sulfonate are not amino acids.

The disclosure is objected to because of the following informalities: on page 8, in paragraph 23, Toluene sulfonate and Benzene Sulfonate are not amino acids.

Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 65, 66, 68-72, 74-81 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodruff.

Woodruff teaches Gabapentin and related species such as the ethyl derivative (column 35-62) in tables, capsules and powders comprising compounds such as Lactose (column 3 line 63-column 4 line 13). An injectable composition, reading on claims 65, 66, 68-81 consists of the active agent and water (example 1 column 8).

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 45-52, 67 are drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is 308-4432. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on 305-1877. The fax phone number for the organization where this application or proceeding is assigned is 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234.


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Webman/tgd

April 7, 2003


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